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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,292	04/10/2001	Alexey Ryazanov	601-1-098CIP	8327

23565 7590 03/11/2003

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,292

Applicant(s)

RYAZANOV, ALEXEY

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 6-13 and 18-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 4, 5 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1-48 are at issue and are present for examination.

Election/Restrictions

Applicant's election of Group II, Claims 4-6 and 14-17, in Paper No. 12 is acknowledged. Further, applicant's response to the previous restriction requirement was incomplete in that applicant did not elect a corresponding molecule from *Homo sapiens* or *Mus musculus* as instructed at the bottom of page 4 of the restriction requirement. As indicated in the attached Interview summary, the examiner called applicant's representative and left a message that the previous response to the restriction requirement, Paper No. 11, 12/17/2002, was not complete for this reason. Applicant's representative called the examiner back and instructed the examiner that the applicants would like to elect the nucleic acid of *Homo sapiens* (SEQ ID NO: 34) in addition to the previously elected Group II.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-3, 6, 7-13 and 18-48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

Applicants amendment of the first line of the specification stating that this application is a continuation-in-part of copending application Serial No. 09/623,131, filed August 3, 2000, of which the instant application claims the benefit of the filing date pursuant to 35 U.S.C. 120 and which is incorporated herein by reference in its entirety, is acknowledged.

It is further noted that applicants claim of priority for the DNA sequence of SEQ ID NO: 34 is only granted to the instant application, filed 4/10/2001, as there is no support for this sequence in application Serial No. 09/623,131.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper

Specification

The disclosure is objected to because of the following informalities:

The description of Figures 1 and 2, while describing parts A and B do not refer to these figure parts the same as Figures 5-11 in which each Description of a figure begins such as "**Figure 6 A-B**". Further the description of Figure 6 is as previously stated

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"Figure 6 A-B" where as the description of Figure 7 is **"Figure 7 A and B"** It is suggested that consistency be maintained throughout the specification.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth: The following portions of the specification list sequences which appear to meet the definition for an amino acid sequence, but do not have an associated SEQ ID No: Page 4, line 20, page 21, line 10.

Appropriate correction is required.

Claim Objections

Claims 4, 5 and 14-17 are objected to because of the following informalities:

Claims 4, 5 and 14-17 are objected to as including non-elected subject matter.

Claims 4, 5 and 14-17 have been examined only with respect to the DNAs of SEQ ID NOS: 34.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 (17 dependent on) is indefinite in the recitation of part j. "DNA sequences that code on expression for an amino acid sequence...". For the purpose of advancing prosecution this recitation is interpreted as "DNA sequences that **encode** [on expression for] an amino acid sequence..."

Claim 4 (5, 14 and 15 dependent on) is indefinite in the recitation of a heart alpha kinase as it is unclear what features define a heart alpha kinase from other alpha kinases. While page 5 defines the characteristics of an alpha kinase, the only definition of the term heart alpha kinase is on page 26 and is wholly unclear as to the scope of proteins encompassed. While it is clear applicants intend this term to encompass the proteins of SEQ ID NOS: 35 and 37 it is also clear that this term is intended to include other similar proteins also. However, the definition does not make clear what the metes and bounds of this term are.

It is noted that applicants recitation in claim 4 of standard hybridization conditions is interpreted as those conditions specified on page 37, lines 11-21 as 5XSSC and 65°C for both hybridization and washes.

Further it is noted that part d of claim 4 which recites "DNA sequences capable of encoding the amino acid sequence encoded by the DNA sequences of subparts (a), (b) or (c)." is interpreted as DNA sequences which are degenerate sequences of the DNA sequences of subparts (a), (b) or (c).

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 16 and 17 are directed to a genus of unicellular host cells transformed with any DNA which encodes any alpha kinase or a fragment thereof, wherein said DNA which will hybridize to SEQ ID NO:34 under standard stringency conditions (Claims 16 and 17).

The specification does not contain any disclosure of the structure and function of all DNA sequences encompassed by the genus of the claims. The claimed genus of host cells comprising the recited DNAs is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a two species of the claimed genus (those host cells transformed with SEQ ID NOS: 34 and 36) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the

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applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell transformed with a DNA molecule comprising SEQ ID NO: 34, does not reasonably provide enablement for any host cell transformed with any DNA sequence which encodes a fragment of SEQ ID NO: 34 or a DNA sequences which hybridizes to a fragment of a DNA sequence which encodes SEQ ID NO: 34. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

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Claims 16 and 17 are so broad as to encompass any host cell comprising any DNA which encodes any fragment of SEQ ID NO: 34 or any DNA which hybridizes under standard hybridization conditions to a DNA sequence which encodes SEQ ID NO: 34. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of host cells comprising the recited DNAs broadly encompassed by the claims, including any host cell which comprises any DNA which hybridizes under standard hybridization conditions to a DNA sequence which encodes SEQ ID NO: 34. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to those host cells which have been transformed with a DNA sequence of SEQ ID NO: 34.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to

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modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any nucleic acid encoding a heart alpha kinase because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting kinase activity; (B) the general tolerance of heart alpha kinases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any heart alpha kinase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the heart alpha kinase activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those host cells of the claimed genus comprising the claimed DNA sequence.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated

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with the scope of the claims broadly including any number of modifications of any DNA encoding any alpha kinase. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Scharenberg et al. (WO 00/40614, July 2000).

Scharenberg teach nucleic acids encoding a protein named SOC-2/CraC-1 with kinase activity and homology to the TRP family of calcium channels. These nucleic acids are clearly encompassed by a DNA which encodes an fragment of an alpha kinase. Scharenberg further teach expression vectors comprising said nucleic acid and host cells transformed there with. Thus Scharenberg anticipates claims 16 and 17.

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Remarks

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a horizontal line extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
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March 7, 2003